IN THE UNITED STATES DISTRICT COURT
FOR EASTERN DISTRICT OF NORTH CAROLINA

SEPRACOR, INC., et al., Plaintiffs, vs. BARR PHARMACEUTICALS, INC., et al. Defendants.	Western Division No. 5:08-CV-362-H(3)
SEPRACOR, INC., et al., Plaintiffs, vs. SANDOZ INC., Defendant.	Eastern Division No. 4:08-CV-89-H(3)
SEPRACOR, INC., et al., Plaintiffs, vs. SUN PHARMACEUTICALS INDUSTRIES, LTD., Defendant.	Western Division No. 5:08-CV-247-H(3)
SEPRACOR, INC., et al., Plaintiffs, vs. SYNTHON PHARMACEUTICALS, INC., et al. Defendants.	Western Division No. 5:08-CV-179-H(3)

SANDOZ'S OPPOSITION TO PLAINTIFFS' MOTION TO EXTEND SANDOZ'S THIRTY-MONTH STAY OF FDA APPROVAL

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I. INTRODUCTION

Sepracor Inc., UCB Inc., and UCB S.A. (collectively, "Sepracor") file this Motion to Extend the Stay as an eleventh-hour effort to maintain market exclusivity of levocetirizine. Sepracor veils its motion in alleged "discovery failures" and "delay." In reality, however, Sepracor seeks a vehicle to prevent an ANDA applicant who chooses a section viii statement, instead of a Paragraph IV certification, from entering the market when the FDA approves the section viii filer's label. Sepracor's actions during this litigation belie its ultimate motive.

Sepracor's position has been that "the 30-month stay is irrelevant and there is no exigency requiring advancement of this case." Ironically, now that Sandoz has filed a section viii statement instead of a Paragraph IV certification, Sepracor pleads that the same stay *is relevant* and should be extended. Sepracor cannot have it both ways, and its motion should be denied for at least three reasons: (1) the Court lacks subject matter jurisdiction over Sandoz's section viii ANDA filing, (2) the 30-month stay is inapplicable to ANDA applicants proceeding under section viii, and (3) Sandoz has not unreasonably delayed this action.

II. ARGUMENT

Statutory stay adjustments are not frequent occurrences. *Eli Lilly & Co. v. Teva Pharms. USA Inc.*, 557 F.3d 1346, 1354 n.2 (Fed. Cir. 2009) (Prost, J., dissenting). "Congress sought to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991). Indeed, courts recognize that a central purpose of the Hatch-Waxman Act is to enable competitors to bring cheaper generic drugs to market as quickly as possible. *See Astrazeneca AB v. Dr. Reddy's Labs. Ltd.*, 603 F. Supp.

2d 596, 599 (S.D.N.Y. 2009) (public interest "makes it imperative that these matters move along as quickly as possible, even if they are complex").

Sandoz has no incentive to delay resolution of this action, and Sandoz has not done so. Ironically, Sepracor accuses Sandoz of delay hoping for further extension of the stay, so that Sepracor can delay ultimate resolution of this action and extend its market exclusivity in sales of levocetirizine. Extending exclusivity confers upon Sepracor substantial benefit. Sepracor's attempt to do so by way of this motion should be denied.

A. The Court Lacks Jurisdiction to Extend the Stay

Sepracor's motion should be denied because the Court has no subject matter jurisdiction over Sandoz's section viii ANDA filing. *See* Sandoz's Motion to Dismiss (filed concurrently herewith). As the Court noted in its order reopening limited discovery into Sandoz's section viii filing, "A section viii filing...allows a generic manufacturer to 'carve out' a label in the method of treating patients to avoid infringement under Paragraph IV.... Sandoz is no longer seeking approval for the use of levocetirizine in the treatment of allergic rhinitis." (Dkt. No. 227, at 3-4). Recognition of this fact is relevant to this Court's subject matter jurisdiction analysis. Sepracor's case is based on Sandoz's Paragraph IV certification that no longer exists.

Sepracor proceeds under 35 U.S.C. § 271(e)(2). However, jurisdiction under section 271(e)(2) requires an ANDA filer maintain a Paragraph IV certification before the U.S. Food and Drug Administration ("FDA"). H.R. Rep. No. 98-857(I), at 46 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2679. Section 271(e)(2) does not confer jurisdiction where the ANDA filer seeks approval from the FDA under "section viii," as Sandoz has done here. *Id.* The Court did not reopen discovery so Sepracor could rehash its section 271(e)(2) case.

Rather, the court reopened discovery for the narrowly tailored purpose of allowing Sepracor to discover information regarding Sandoz's section viii filing and its forecasts for the patented method in support of a potential section 271(b) inducement case.

Thus, neither Sandoz's section viii filing nor the Court's August 9, 2010 Order provides a basis for extending the 30-month stay conferred by a Paragraph IV filing that no longer exists. This case is ripe for dismissal. For this reason, the Court should deny (or hold in abeyance) Sepracor's Motion to Extend the Stay unless and until the Court determines that it has subject matter jurisdiction over this action. *University of South Alabama v. American Tobacco Co.*, 168 F.3d 405, 410 (11th Cir. 1999) ("Simply put, once a federal court determines that it is without subject matter jurisdiction, the court is powerless to continue." (citation omitted)); *Wernick v. Matthews*, 524 F.2d 543, 545 (5th Cir. 1975) ("[W]e are not free to disregard the jurisdictional issue, for without jurisdiction we are powerless to consider the merits."); *Cowin Equip. Co. v. Wirtgen Am., Inc.*, No. 06-00458, 2006 WL 783364, *1 (N.D. Ga. Mar. 24, 2006) (refraining from ruling on motion to stay until issues of subject matter jurisdiction were resolved) (attached hereto as Exhibit A).

B. The 30-Month Stay is Inapplicable to Sandoz's Section viii Statement

With its section viii statement, Sandoz is not seeking FDA approval for use of levocetirizine to treat allergic rhinitis, the patented method. Unlike a Paragraph IV certification, Sandoz does not challenge the listed patent. Likewise, in a situation where litigation was not already ongoing, a section viii statement does not necessitate notice to the NDA holder or patent owner, and does not trigger a 45-day window in which the patent owner may file suit and impose a 30-month stay. *See Purepac Pharm. Co. v. Thompson*, 238 F. Supp.2d 191, 195 (D.D.C. 2002) ("An applicant proceeding by means of a section viii

statement … does not face an infringement action under 35 U.S.C. § 271(e)(2)(A) … or the automatic 30-month stay applicable to paragraph IV certifications should the owner decide to file an infringement action."). Section viii statements simply do not have an associated stay provision.

Contrary to Sepracor's assertions, *Bayer Healthcare LLC v. Norbrook Labs., Ltd.*, No. 08-00953, 2009 WL 6337911, at *8 (E.D. Wis. Sept. 24, 2009) (attached hereto as Exhibit B) does not stand for the proposition that an ANDA application who files a Paragraph IV certification and later attempts to withdraw it for a section viii statement does not avoid the 30-month stay. Rather, *Norbrook Labs.* stands for the proposition that an infringement case under § 271(e)(2) may still be maintained regardless of the certification in the ANDA, as long as the purpose of the submission is to obtain approval to engage in the commercial use of a drug *claimed in a patent*. *Id.* at *9 (emphasis added). Sandoz is not seeking approval for the patented method of use. *See* 21 U.S.C. § 355(j)(2)(A)(vii), (viii). Hence, *Norbrook Labs.* is inapposite because it does not address a section viii statement's effect on the 30-month stay.

Since Sandoz is no longer pursuing FDA approval under paragraph IV, the 30-month stay is no longer applicable and no extension should be granted. Applicants submitting section viii statements need not wait 30 months for FDA approval. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004). Thus, the Court should deny Sepracor's motion to extend the stay.

C. Sandoz Sought to Expedite—Not Delay—This Action

Prior to conversion from a Paragraph IV certification to a section viii statement, Sandoz affirmatively sought to expedite resolution of the case before expiration of the 30-

month stay.[1] (Dkt. No. 149) In response to that motion, Sepracor argued that "the 30-month stay is irrelevant and there is no exigency requiring advancement of this case." (Dkt. No. 150, at 2) It is ironic that the stay suddenly is relevant to Sepracor when it has become statutorily inapplicable. This about-face exposes Sepracor's motion as a contrived litigation tactic designed to protect Sepracor's market exclusivity. In fact, co-defendant Synthon's 30-month stay has already expired, yet Sepracor has not filed a similarly-captioned motion against Synthon. Both this case and Sepracor's case against Synthon proceed at the same pace to trial.

Sandoz has cooperated in moving this action forward; after all, it is in Sandoz's best interest to obtain a decision here. Sepracor's overreaching statement that "at each stage of this case Sandoz has failed to cooperate and has caused delay" is belied by the events leading up to Sepracor's current motion. For example, Sepracor has previously telegraphed its intent to slow down this case, suggesting that resolution of the claim construction issues will not "necessarily make this case ready either for trial or summary judgment." (*Id.* at 4). However, contrary to Sepracor's assertions, with a claim construction ruling imminent, and fact and expert discovery closed over a year ago, nothing prevents this case from moving towards summary judgment or trial. However, Sepracor's prolific motion and letter practice before this Court and filings with the FDA show its aggressive attempt to slow this case and

[1] If, prior to the expiration of the 30-month stay, the district court determines that the patent in suit is invalid or not infringed, the 30-month stay is terminated and the FDA can approve the generic drug. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I).

approval of Sandoz's levocetirizine product.[2] Any allegations of delay stemming from Sandoz's section viii statement are pretext.

After learning of Sandoz's section viii statement, Sepracor delayed for two months before filing its motion to reopen discovery. (*See* Dkt. No. 206). The Court reopened discovery on August 9, 2010 for the limited purpose of discovery regarding Sandoz's proposed label and forecasts of prescriptions for the patented method. (Dkt. No. 227). The limited order did not relate to the substantive issues of § 271(e)(2) infringement or invalidity of the patent in suit.

Contrary to Sepracor's statement that "there has been little progress on discovery," Sandoz completed its document production on October 22, 2010, and a 30(b)(6) deposition is scheduled for November 23, 2010. (Ex. C, 10/22/10 Pluta email to Tempesta; Ex. D, 10/27/10 correspondence regarding deposition). Thus, Sandoz has not "failed to reasonably cooperate in expediting this action."

Further, this satellite discovery has done nothing to slow this case's readiness for trial. Prior to the Court's August 9 Order, claim construction briefing was complete, general and expert discovery were closed, and the Court had indicated that it would schedule the case for trial once the claim construction was determined. (Dkt. No. 36). Nothing in the Court's August 9 Order changed that status.

1. Case Law and Legislative History Support Sandoz and Do Not Support Extending the Stay

Case law does not support extending the stay. In *Minnesota Mining and Mfg. Co. v. Alphapharm Pty. Ltd.*, No. 99-cv-00013-MJD-JGL, Dkt. No. 105 (D. Minn. April 2, 2001)

[2] *See, e.g.,* Motion for Leave under Protective Order re Citizen Petition (Dkt. No. 243); 10/15/10 Letter to Judge Webb re Citizen's Petition (Dkt. No. 261).

(attached hereto as Exhibit E), the court denied a request to extend the stay where 3M asserted the defendant delayed the litigation by challenging jurisdiction, not timely responding to discovery requests, and amending its ANDA. *Id.* at 3. The court modified the litigation schedule, but declined to extend the stay. After reviewing the legislative history, the court determined that Congress necessarily considered the possibility of the statutory bar expiring before the litigation was resolved and rejected imposing stays coincident with the period of litigation. *Id.* at 7-8 (citing *Zeneca Ltd. v. Pharmachemie B.V.*, 16 F. Supp. 2d 112 (D. Mass. 1998) ("[t]hat the statutory bar might expire prior to a ruling on the validity of the patent was anticipated and accepted by the legislators..."). The *3M* court noted that, although Alphapharm incidentally caused delay when it challenged discovery requests and amended its ANDA, it found that those actions were legally supportable and thus insufficient to conclude that Alphapharm took those actions for the improper purpose of delaying litigation. *Id.* at 9.

Similarly, Sandoz's section viii statement, discovery challenges, and jurisdictional challenge are all legally supportable actions. Moreover, any alleged delay caused by Sandoz in responding to discovery with respect to its labeling changes has not delayed ultimate resolution of this matter, and Sepracor has not shown any prejudice. Indeed, should a party begin marketing its product, Hatch-Waxman legislative history supports the position that subsequent damages, not extension of the stay, are the proper remedy.[3] *See 3M*, Dkt. No.

[3] Sepracor's Motion to Extend the Stay is a creative way of seeking relief more appropriately requested in a motion for preliminary injunction. *See Minn. Mining & Mfg. v. Alphapharm Pty., Ltd.*, No. 99-00013, 2002 WL 1299996, at *3 (D. Minn. Mar. 8, 2002) (attached hereto as Exhibit F). Yet, Sepracor cannot meet the heavy burden for issuance of a preliminary injunction, including timeliness. Sepracor will not be irreparably harmed by Sandoz introducing a levocetirizine product for treatment of urticaria.

105 at 8 (citing H.R. Rep. No. 98-857, pt. 2, at 9 (1984)); *Bayer Schera Pharma AG v. Sandoz Inc.*, 2010 WL 3447906, at *3 (S.D.N.Y. Sept. 2, 2010) (same) (attached hereto as Exhibit G); *see also 3M v. Alphapharm*, 2002 WL 1299996, at *3 (denying second request for extension for stay and motion for preliminary injunction, noting that irreparable injuries are those that cannot be measured in monetary terms).

2. Sepracor's Cases Do Not Support Extension of The 30-Month Stay Here

The cases cited by Sepracor do not to support extending the stay. For example, in *Eli Lilly* the district court extended the stay by 4 months until the beginning of trial. 557 F.3d at 1349. However, Teva had made a substantive change to a measuring methodology of an active ingredient in the generic product with only eight months until trial. *Id.* The parties were still conducting additional discovery on Teva's product alteration up until three months before trial. *Id.* The district court found that, "in preparation for trial, Lilly is entitled to have sufficient opportunity to identify the nature and composition of the reloxifene product as Teva intends for it to be sold." *Id.* at 1350. Here, unlike *Teva*, no trial date is scheduled. Indeed, Sepracor makes no claim of delay that prejudices its preparation for trial, nor could it. Further, unlike the product amendment in *Teva*, Sandoz's section viii amendment streamlines, rather than complicates, the action because the cause of action for infringement no longer lies.

Eli Lilly & Co. v. Zenith Goldline Pharms., No. 99-00038, 2001 WL 238090, at *1 (S.D. Ind. Mar. 8, 2001) (attached hereto as Exhibit H) is similarly inapplicable. In *Zenith*, the court found that Zenith failed to reasonably cooperate in expediting the action by failing to timely serve its expert reports on invalidity, "the central issue of the case." *Id.* Zenith

represented to the court that it could not serve its reports until approximately thirty days prior to trial, thus the court extended the stay because resolution of the case would be delayed. *Id.* Unlike in *Zenith*, Sandoz has not failed to serve reports and there is no trial date to reschedule. Indeed the Court has previously indicated that it would calendar a trial date only after resolution of claim construction issues. (Dkt. No. 36). Claim construction is fully briefed and under recommendation by the Magistrate; Sepracor's objections to the Magistrate's recommendation keep claim construction from being fully resolved. Hence, the limited discovery relating to Sandoz's section viii statement has no effect on the progress of claim construction proceedings.[4]

Sepracor's reliance on *Janssen Pharm. N.C. v. Eon Labs. Mfg., Inc*, 374 F. Supp. 2d 23 (E.D.N.Y. 2004) is similarly misapplied. In *Janssen*, the court extended the stay for six months until the beginning of trial based on Eon's "delay of litigation." No analysis of the nature of Eon's delay was disclosed, but the court did state that it would be improper to extend the stay any longer unless the plaintiff's remaining claim of infringement was viable. (*Janssen*, No. 01-02322, Dkt No. 131) (attached hereto as Exhibit I). Here, Sepracor lacks a viable infringement claim against Sandoz by virtue of Sandoz's section viii statement. So, the logic of *Jansen* supports denial of extension of the stay.

Sepracor's request for a nine-month extension of the stay is unreasonable and should be denied because there is no evidence that Sandoz failed to reasonably cooperate in expediting resolution of this case.

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[4] In fact, Sepracor continues to delay resolution of the claim construction issues by requesting leave to file a reply in its briefing on objections to the Magistrate Judge's recommendation on claim construction. (*See* Dkt. No. 265). *See* Local Civil Rule 7.1(f) (providing for oppositions and responses, but not replies, to a magistrate's recommendation).

III. CONCLUSION

Because this Court lacks subject matter jurisdiction over Sandoz section viii ANDA filing, because a 30-month stay is inapplicable to a section viii filing, and because Sandoz did not unreasonably delay, Sandoz requests that the Court deny Sepracor's motion to extend Sandoz's thirty-month stay of FDA approval.

November 3, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2010, I electronically filed the foregoing **SANDOZ'S OPPOSITION TO PLAINTIFFS' MOTION TO EXTEND SANDOZ'S THIRTY-MONTH STAY OF FDA APPROVAL** with the Clerk of the

Court using the CM/ECF system which will send notification of such filing to all counsel of record.

Respectfully submitted,

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